DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region 5191d

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

May 17, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Chuck Loper
Herdsman
Tallmon Dairy
6510 McNutt Rd.
Santa Teresa, NM 88008

Ref. #: DEN-04-08

Dear Mr. Loper:

Consumer Safety Officer Tricia Y. Samaniego conducted an inspection of your dairy operation, Tallmon Dairy, 6510 McNutt Rd., Santa Teresa, NM on February 4 & 5, 2004. The inspection confirmed that you offered animals for sale for slaughter as food, in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. You sold dairy cows on X separate occasions to X X X X X X X X X X X X X which were found to contain illegal levels of drug residues by USDA testing.

recorded under USDA case No. 03-1105-TX include:

X X X USDA analysis of tissue samples collected from your dairy cow with ear tag X (USDA Sample No. 416012) identified the presence of sulfadimethoxine residue of 14.04 parts per million (ppm) in the liver and 9.20 ppm in the muscle. A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in the uncooked edible tissues of cattle in Title 21 Code of Federal Regulations 556.640 (21 CFR 556.640).

X X X X X: USDA analysis of tissue samples collected from your dairy cow with ear tag X (USDA Sample No. 416021) identified the presence of sulfadimethoxine residue of 3.32 ppm in the liver and 1.68 ppm in the muscle.

X X X X USDA analysis of tissue samples collected from your dairy cow with ear tag ? (USDA Sample No. 416014) identified the presence of oxytetracycline residue of 69.63 ppm in the

kidney and 7.39 ppm in the muscle. A tolerance of 12 ppm has been established for residues of oxytetracycline in the kidney and 2 ppm in the muscle of cattle in 21 CFR 556.500.

During our investigation, you reported that your firm treated dairy cow with ear tag No. [redacted] with [redacted], and dairy cow with ear tag No. [redacted] with [redacted] and [redacted] The presence of this drug in uncooked edible tissue from these animals in amounts exceeding the tolerance set out in 21 CFR 556.640 causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act. You also reported that your firm treated diary cow with ear tag No. [redacted] with [redacted] The presence of this drug in the edible tissue from this animal in amounts exceeding the tolerance set out in 21 CFR 556.500 causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions whereby . . . it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues, and you lack an adequate inventory system for determining the quantities of drugs used to medicate your cows.

As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law. Failure to do so may result in regulatory action, without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to H. Tom Warwick, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. He may be reached at (303) 236-3054 if you have any questions about this matter.

Sincerely,

B. Belinda Collins
District Director

cc: Mr. Ronald K. Jones, D.V.M
Boulder District Manager
USDA/FSIS
665 S. Broadway, Suite B
Boulder, CO 80303